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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/184,043 11/02/98 HORNAUER

H P564-8023

EXAMINER

CEPERLEY, M

ART UNIT	PAPER NUMBER
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1641

11

DATE MAILED:

07/24/00

HM12/0724
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/184,043

Applicant(s)

HORNAUER et al

Examiner

Mary E. Ceperley

Group Art Unit

1641



☒ Responsive to communication(s) filed on May 1, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-12, 14-26, and 28-42 is/are pending in the applicat

Of the above, claim(s) 1-7, 14-26, 28-38, 41, and 42 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 8-12, 39, and 40 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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1. Applicants' election without traverse of claims 8-12, 39 and 40 in Paper No. 9 is acknowledged. Claims 8-12, 39 and 40 are treated on the merits in this Office action. Claims 1-7, 14-26, 28-38, 41 and 42 are withdrawn from further consideration as being drawn to non-elected inventions.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-12, 39 and 40 are rejected under 35 USC 112, first paragraph, as not corresponding with the enabling written description of the invention as it is set forth in the specification and/or as being based on a specification which does not contain an adequate enabling written description.

a). There is no description in the specification of the term "I" defined as "an inert carrier" in claim 8. Although page 5, the third line from the end, defines "I" as "a biomolecule", there is no written description of the term "biomolecule".

b). The structures depicted in claim 8 are inconsistent with the "conjugates" which are described and enabled by the description. For example, although the structures of the conjugates of the claim are depicted as containing no additional unspecified linkage between the "P_r" and

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“(AO)” moieties, the conjugates prepared in Examples 1 and 2 contain an additional linking moiety.

c). The structures depicted in claim 8 are inconsistent with the “conjugates” which are described and enabled by the description. If “T” were as defined in claim 8, the terminal moieties in each of structure (Ia) and (Ib) would be groups such as “(AO)OH”, “(AO)OCH₃” or “(AO)C(O)CH₃” for which there is no enablement in the specification. See Examples 1 and 2.

d). Enablement in the specification is limited to the preparation of the conjugates of Examples 1 and 2. The specification contains neither a specific description of the preparation of any other conjugate nor a generic description of any method of preparation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-12, 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and/or incomplete.

a). A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10

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USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation "T is an end group", and the claim also recites "preferably selected from..." which is the narrower statement of the range/limitation.

b). Claims 11 and 12 are incomplete and indefinite in not reciting adequate method steps to define the recited methods of use.

c). It is unclear what is meant by the term "inert carrier" of claim 8. What is carried by the "carrier" and for what purpose is it "inert"?

d). The claims are indefinite in not defining the moiety through which "Pr" is linked to "I" or "(AO)" and through which "I" is linked to "(AO)".

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8-12, 39 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or alternatively under 35 U.S.C. 103 as obvious over Zalipsky [Bioconjugate Chem., Vol. 6, pp. 150-165 (1995)].

Zalipsky describes conjugates of PEG and a wide variety of ligands which are described as having an array of useful properties (see the entire article, in particular, Tale 1.). These conjugates anticipate the PEG-ligand conjugates of the instant claim 8. The features of the dependent claims are either specifically described by the reference (e.g. claim 10 solid phase containing PEG conjugate: see first paragraph of the Introduction; claim 11 reduction of non-specific binding: see page 158, second column, first paragraph under the structures) or constitute obvious modifications of parameters which are routinely varied in the art (e.g. specific biotin

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ligand of instant claim 9) and which have not been described as being critical to the practice of the invention. The packaging of components in kit form (claims 39 and 40) is a well known, obvious expedient for convenience in assay performance.

9. Claims 8 and 9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Eaton et al [U.S. 6,047,698], Sluka et al [U.S. 5,932,296], Reichert et al [U.S. 5,832,165] or Herron et al [U.S. 5,677,196].

Each of the references describes a biotin-PEG conjugate which anticipates the conjugate of instant claim 9. See Eaton et al: col. 40, Example Two; col. 45, lines 1-19; Sluka et al: Fig. 2; Reichert et al: col. 15; lines 63-67; Herron et al ('196): Example IV.

10. Claims 10, 11 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hammen [U.S. 5,240,602] or Herron et al [U.S. 5,512,492].

Hammen and Herron et al each describe a ligand-PEG conjugate on a solid phase which anticipates the solid phase of instant claim 10 and its use in an immunoassay for the purpose of reducing non-specific binding. See Hammen: Example 23 and col. 4, lines 42-47; Herron et al: claims 24 and 25. The packaging of components in kit form (claim 40) is a well known, obvious expedient for convenience in assay performance.

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11. Claim 10 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over ~~each of~~ Ofsthun et al [U.S. 5,871,649].

Ofsthun et al describe a ligand-PEG conjugate on a support which anticipates the solid phase of instant claim 10. See Ofsthun et al: col. 14, lines 17-61.

12. Claim 8 is rejected under 35 U.S.C. 102(b)/(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kricka [U.S. 5,306,621], Theodore et al [U.S. 6,015,897] or Van Alstine [U.S. 5,108,568].

Each of the references describes a ligand-PEG conjugate which anticipates the conjugate of instant claim 8. See Theodore: col. 28, line 18-39; Kricka: Example 5; Van Alstine: col. 7, lines 33-45.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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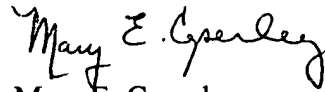
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July 20, 2000

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Mary E. Ceperley

Primary Examiner

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